Paramesh Banerji Life Sciences Group Presentation to FDA

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Our Background

- **We at Paramesh Banerji Life Sciences Group bring a unique and most wide and deep understanding of all aspects of Homeopathy. This is based on our:**
  - **97 years of uninterrupted experience**
  - **Having the world's largest body of evidence**
  - **Global Perspective about Homeopathy**

Our Background

97 years of uninterrupted experience in:

- **Homeopathic Healthcare Service Delivery**
- **Homeopathic Medicine Manufacturing**
- **Homeopathic Clinical Research**
- **Homeopathic Practitioner Training**

Our Background

- **Having the world's largest body of evidence from:**
  - **The most well documented cases with medical records like blood works and scans**
  - **Millions of prescriptions served**
- **Having the widest range of diseases treated using Homeopathy**

Our Background

- **Our Global Perspective about Homeopathy from:**
  - **Our point of presence in India, UK and USA**
  - **Our patients come from 87 countries**
  - **All manner of backgrounds from deep rural communities in 3rd world countries to European and North American metropolis**

Why are we presenting today?

- **We are speaking here today to register the point that we are going to present a very detailed written submission covering our views on every aspect of the Homeopathic regulatory framework within the 22nd of June 2015 deadline.**

Our Responses to FDA Questions

- **Our written detailed submissions by 22nd June 2015 will cover all the aspects mentioned in the FDA's notice, a summary of which is given in this presentation.**

FDA Question 1

- **1. What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic?**

Question 1: Our Response

Consumer Perspective:

- **i) They are the safest medicinal substances known to man**
- **ii) In case they don't help they will never harm**

Question 1: Our Response *contd…*

- **Healthcare Service Provider - mainly medical practitioners:**
- **i) Many conventional medicine practitioners either refer some of their patients to Homeopaths or they themselves prescribe Homeopathic medicines to help patients where conventional medicines fail to deliver. The percentage varies widely between countries.**

Question 1: Our Response *contd…*

- **Healthcare Service Provider - mainly medical practitioners:**
- **ii) Many other conventional medicine practitioners think that Homeopathic medicines don’t have any medicinal property and therefore by extension confirm that they cannot harm the patient even if it cannot help them.**

FDA Question 2

- **2. What data sources can be identified or shared with FDA so that the Agency can better assess the risks and benefits of drug and biological products labeled as homeopathic?**

Question 2: Our Response

- **The only data sources that can be of meaningful benefit to the FDA are from Homeopathic Healthcare Service providers (wherever they are in the world) that have a statistically significant number of prescriptions served - at least 10,000+ per year.**

Question 2: Our Response *contd…*

- **We will be willing to support the FDA significantly in this matter with the assumption that the appropriate resources for evaluation of the information/evidence/data are made available.**

FDA Questions 3 & 4

- **3. Are the current enforcement policies under the CPG appropriate to protect and promote public health in light of the tremendous growth in the homeopathic drug market? Are there alternatives to the current enforcement policies of the CPG that would inform FDA's regulatory oversight of drugs labeled as homeopathic? If so, please explain.**
  - **AND**
- **4. Are there areas of the current CPG that could benefit from additional clarity? If so, please explain.**

Questions 3 & 4: Our Response

- **In summary the enforcement policies are adequate and in principle we are one with AAHP in this matter.**

Questions 3 & 4: Our Response *contd...*

- **The only area of improvement can come from FDA's better understanding of the circumstances under which Homeopathic products are used, prescribed or resorted to by patients.**

Questions 3 & 4: Our Response *contd...*

- **Also a better understanding of what the term Homeopathic products represent in the current context in terms of the substance, process of manufacture and also the categories they may be classified for better regulation.**

Questions 3 & 4: Our Response *contd...*

- **We are going to submit a detailed documentation to cover these aspects because we feel it is essential for the FDA to have these perspectives for better policy making.**

FDA Question 5

- **5. Is there information regarding the regulation of homeopathic products in other countries that could inform FDA's thinking in this area?**

Question 5: Our Response

- **i) We do not feel that FDA should look at regulatory guidelines from any other country.**
- **ii) FDA should be an opinion leader it normally is for the International community.**

Question 5: Our Response *contd…*

- **FDA should use this Public consultation as the platform to create the new perspective for regulatory framework for Homeopathy in the USA, which other countries can look up to.**
  - **We will be submitting detailed documentation on this subject in our written submission.**

FDA Question 6

Given the wide range of indications on drug products labeled as homeopathic and available OTC, what processes do companies currently use to evaluate whether such products, including their indications for use, are appropriate for marketing as an OTC drug?

Question 6: Our Response

- **In this regard we will be submitting detailed documents covering all aspects of this very important issue.**

  Some key pointers are given in the next slides …

Question 6: Our Response *contd...*

- **i). The current practices related to labelling borrow the shortcomings from the anomalies surrounding the policies about who can prescribe or suggest Homeopathic medicines in the USA.**

Question 6: Our Response *contd…*

- **ii). The limitations also arise from the dichotomy between the very nature of Homeopathic products and the current mandatory labelling requirements.**

Question 6: Our Response *contd…*

- **iii). The overarching conclusion about the validity of Homeopathic products being put in the category of OTC is supported by the scientific fact that being diluted natural substances they are safe and can pose no threat to the user.**

Question 6: Our Response *contd…*

- **There are numerous other aspects and perspectives that need FDAs understanding and consideration, which we will be including in our detailed written submission within 22nd June 2015.**

FDA Questions 7 and 8

7. Do consumers and health care providers have adequate information to make informed decisions about drug products labeled as homeopathic? If not, what information, including, for example, information in labeling, would allow consumers and healthcare providers to be better informed about products labeled as homeopathic?

- **AND**

8. A large majority of human drug products labeled as homeopathic are marketed as OTC drugs. These products are available for a wide variety of indications, and many of these indications have never been considered for OTC use under a formal regulatory process. What would be an appropriate regulatory process for evaluating such indications for OTC use?

Questions 7 & 8: Our Response

- **i) We feel there is scope for improvement in this area.**
- **ii) However, labelling only may not be the only way in which this information gap can be filled.**

Questions 7 & 8: Our Response *contd...*

- **We will be submitting detailed documentation on this subject with some suggestions based on our 360 degree understanding about how Homeopathic products are made, labelled, prescribed, perceived, bought, used and experienced by the user in every possible context.**

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